IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

No. 5:08-MD-1959-BO

IN RE:	)	
	)	
PANACRYL SUTURES PRODUCTS	)	
LIABILITY CASES	)	ORDER
	)	
	)	

This matter is before the Court on Defendants' Motion for Protective Order (DE # 123), Plaintiffs' Motion to Compel (DE # 127), and Plaintiffs' Motion to Seal (DE #142). Defendants move to modify the subpoena duces tecum served on Dr. Leo B. Gibney, Jr., to exclude a list of physicians who used Panacryl Sutures and to limit the scope of the deposition of Dr. Gibney to exclude questions regarding that list. Plaintiffs' Motion to Compel seeks all complaints received by the Defendants regarding Panacryl Sutures rather than the limited disclosure already provided by Defendants. Plaintiffs' Motion to Seal requests that the Court seal the proposed memorandum and exhibits filed in support of Plaintiffs' Motion for Reconsideration. For the reasons set forth herein, Defendants' Motion for Protective Order and Plaintiffs' Motion to Compel are GRANTED, and Plaintiffs' Motion to Seal is GRANTED in part and DENIED in part.

I. Motion for Protective Order

Defendants argue that 21 C.F.R. § 20.63(f) prohibits the disclosure of a list of physicians provided to Dr. Gibney. 21 C.F.R. § 20.63(f) provides:

> The names and any information that would identify the voluntary reporter or any other person associated with an adverse event involving a human drug, biologic, or medical device product shall not be disclosed by the Food and Drug Administration or by a manufacturer in possession of such reports in response to a

> request, demand, or order. Information that would identify the voluntary reporter or persons identified in the report includes, but is not limited to, the name, address, institution, or any other information that would lead to the identities of the reporter or persons identified in a report. This provision does not affect disclosure of the identities of reporters required by a Federal statute or regulation to make adverse event reports. Disclosure of the identities of such reporters is governed by the applicable Federal statutes and regulations.

As the Sixth Circuit explained in *York v. Am. Med. Sys. Inc.*, No. 97-4306, 1998 WL 863790, *4 (6th Cir. Nov. 23, 1998), "We interpret § 20.63 as granting a blanket prohibition against disclosure of confidential information by manufacturers, subject to the exceptions contained in § 20.63. Sections 20.83 and 20.86, based on their language, carve out a limited exception for the FDA, not manufacturers, to disclose documents in its possession." The Court reasoned that "[t]he entire reporting scheme of the FDA is based on confidential reporting by manufacturers, physicians, and patients. To encourage voluntary reporting, it is necessary to ensure reporters that their information will be kept in confidence and not cavalierly disclosed in various litigation." *Id.* at *5.

Plaintiffs argue that Dr. Gibney was a consultant rather than a manufacturer and that the physicians he contacted were not voluntary reporters within the meaning of 21 C.F.R. § 20.63(f). Plaintiffs are trying to get from Dr. Gibney what they could not get from the Defendants. The Defendants provided the list to Dr. Gibney in order to perform a survey regarding Panacryl Sutures. In light of the policy of encouraging voluntary reporting, it would be inapposite to hold that 21 C.F.R. § 20.63(f) does not apply to a survey commissioned by a manufacturer or where a physician voluntarily responds to a survey undertaken by a manufacturer. As such, this Court concludes that 21 C.F.R. § 20.63(f) exempts the list from discovery.

Therefore, Defendants' Motion for Protective Order is GRANTED. The Gibney

Subpoena shall be modified to bar the disclosure of names, addresses, and phone numbers of health care providers, which include but are not limited to physicians and institutions, who voluntarily reported an adverse event involving Panacryl sutures to Ethicon, Inc. It is further ordered that Dr. Gibney shall not be questioned during his deposition about the identity, including but not limited to questions about the names, addresses, and phone numbers, of health care providers who voluntarily reported an adverse event involving Panacryl sutures to Ethicon, Inc.

The Stipulated Protective Order entered by this Court on April 2, 2009 (DE #70) shall be modified to provide that counsel who receives information about the identity of any health care providers from Dr. Gibney – whether that information is contained in documents produced by Dr. Gibney or whether that information is provided in deposition testimony – shall request that Dr. Gibney provides names of patients who may have had Panacryl sutures used in surgery or forward such information to any person not bound by this Order.

II. Motion to Compel

Plaintiffs have requested from Defendants all complaints related to Panacryl Sutures in the Defendants' possession. Defendants argue that they have produced complaints before each individual Plaintiff's surgery that involved the same or similar surgeries or injuries. Therefore, Defendants argue that further production would be irrelevant to Plaintiff's claims and present an undue hardship because the only remaining documents were received after each individual Plaintiff's surgeries or arose from different surgical procedures. Def. Mem. at 4.

"Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense - including the existence, description, nature, custody, condition, and

location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter." Fed. R. Civ. P. 26(b)(1). Defendants argue that the production sought is not relevant to Plaintiffs' claims. But incidents of injury relate to Panacryl Sutures after an individual Plaintiff's alleged injury may well prove relevant to whether Panacryl Sutures were defectively designed an manufactured. And an injury or lack of injury occurring across various surgical procedures would also be relevant to Plaintiffs' claims.

Therefore, Plaintiffs' Motion to Compel is GRANTED. Defendant Ethicon, Inc. is hereby ordered to produce all complaints, complaint forms, or complaint summaries created an maintained by Defendants that relate in any way to Panacryl Sutures from inception of the product through present. But any such production may be redacted in order to comply with 21 C.F.R. § 20.63(f).

III. Motion to Seal

Plaintiffs' proposed memorandum in support (DE #135) and the attachments thereto do not contain confidential information. Rather, the memorandum contains a legal argument. Attachments 1 and 2 are unpublished opinions. Attachments 3 through 14 contain summaries of state law. Attachment 15 is the Plaintiffs' proposed trial plan. Attachment 16 is a joint pre-trial memorandum originally filed in the Superior Court of Massachusetts. And Attachment 17 is a list of exhibits. These documents do not contain proprietary, scandalous, or confidential information and therefore the Motion to Seal is DENIED with respect thereto. The clerk is directed to unseal DE #135.

Good cause having been shown, the Motion to Seal is GRANTED with respect to Plaintiffs' proposed exhibits - DE # 136, 137, 138, 139, 140, and 141. These entries shall be

sealed.

SO ORDERED, this 1 day of August, 2010.

TERRENCE W. BOYLE
UNITED STATES DISTRICT JUDGE